**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**

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| **IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION** | **Case No. 1:14-CV-01748**<br><br>**MDL 2545**<br><br>**JUDGE MATTHEW F. KENNELLY** |

**This Document Relates to All Cases**

**REPLY IN SUPPORT OF ABBVIE'S SUBMISSION IN SUPPORT OF ENTRY OF PROPOSED CASE MANAGEMENT ORDER REGARDING *EX PARTE* COMMUNICATIONS WITH PHYSICIANS**

## INTRODUCTION

The submission of the Plaintiffs' Steering Committee ("PSC") demonstrates why AbbVie's proposed discovery order is needed. The PSC's intention in meeting *ex parte* with Plaintiffs' physicians is *not* to discuss their clients' personal and confidential medical information, which might in some jurisdictions be subject to a physician-patient privilege. Rather, the PSC wants a court-sanctioned right to coach doctors to give testimony favorable to their cases. In fact, the PSC admits that they would go so far as to use *ex parte* meetings to ***change*** what physicians remember and currently believe about AndroGel – a medicine that is still FDA licensed and prescribed to patients. *See* Pl.'s Submission at 4-5. Rather than letting doctors' best and most honest recollections come out on the record at depositions, the PSC admits that they want to school doctors in their own cherry-picked version of the "facts" about AndroGel and AbbVie. AbbVie's proposed order gives Plaintiffs as much or more than they can reasonably expect by way of protection of a physician-patient privilege, while preventing the bellwether process from suffering this kind of taint.

## ARGUMENT

Plaintiffs' brief provides no legitimate explanation for why they should be allowed to prime doctors to testify differently from how the doctors would without Plaintiffs' lawyers' prior "woodshedding." *See In re Ortho Evra Prods. Liab. Litig.*, No. 1:06-400000, 2010 WL 320064, at *2 (N.D. Ohio Jan. 20, 2010). They offer no reason why they should be allowed to create in doctors – including doctors who may not even have prescribed AndroGel – new "opinions" and "impressions" about AbbVie's medicine and AbbVie generally.[1] The discovery orders cited by the PSC are not apposite. There is no weight of discovery authority in the PSC's favor.

[1] Because the PSC fails to attach a proposed order, it is difficult to know exactly what they are asking the Court to order. It appears their request is that they be given carte blanche to do as they please, while AbbVie has its hands tied, even as to scheduling matters.

Moreover, the PSC's claim that they need the opportunity to undo physician bias in favor of AbbVie, allegedly created by AbbVie's historical sales and marketing efforts, is both illogical and based on nothing but their own say-so. It is not a reason to let Plaintiffs' lawyers engage in pre-deposition one-on-one litigation coaching sessions of doctors.

### A. There is No Weight of Authority Allowing Plaintiffs' Unfettered Right to Coach Doctors Before Their Depositions as Fact Witnesses in these Cases

Plaintiffs assert that "[a]llowing counsel for Plaintiffs – and only counsel for Plaintiffs" to contact physicians *ex parte* "has become almost commonplace." Pl.'s Submission at 5. This is not true. In fact, there are conflicting authorities and multiple courts have prohibited unfettered contacts for exactly the reasons AbbVie set forth in its opening submission. *See, e.g.*, *In re Chantix (Varenicline) Prods. Liab. Litig.*, No. 2:09-CV-2039-IPJ, 2011 WL 9995561 (N.D. Ala. June 30, 2011); *In re Ortho Evra Prods. Liab. Litig.*, 2010 WL 320064 at *2; *In re Nuvaring Prods. Liab. Litig.*, No. 4:08MD1964 RWS, 2009 WL 775442 (E.D. Mo. Mar. 20, 2009); *In re Actos Prods. Liab. Cases*, LASC Case No. BC411687 (Cal. Super. Ct. Mar. 20, 2015);[2] *In re Pelvic Mesh/Gynecare Litig.*, Dkt. No. ATL-L-6341-10 at 6-7 (N.J. Super. Ct. Dec. 3, 2013).[3] Indeed, as recently as the *In re Actos* litigation, courts have recognized that the right of Plaintiffs' counsel to privately discuss their client's medical record does not extend to coaching doctors on all aspects of their case using select documents that the doctor may never have seen and that might not even be the type any doctor would see in making medical decisions for a patient.[4] It is simply not the case that allowing plaintiffs unqualified *ex parte* access has become "commonplace."

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[2] Excerpts attached as Ex. 3 to AbbVie's Submission, Dkt. No. 1143-3.

[3] Attached as Ex. 4 to AbbVie's Submission, Dkt. No. 1143-4.

[4] It is worth noting that it appears the PSC would propose to have the right to discuss AbbVie's sales and marketing, as well as scientific and regulatory documents, even with treating doctors who never prescribed AndroGel to the plaintiff or to any patient. They might well use these documents, for example,

In support of their position that they should have unqualified *ex parte* access, Plaintiffs primarily rely on a decade old opinion from the Vioxx MDL, which is not directly on point. Pl.'s Submission at 5; *In re Vioxx Prods. Liab. Litig.*, 230 F.R.D. 473 (E.D. La. 2005). The issue addressed in the *Vioxx* order was ***not*** whether some limitations should be placed on the *ex parte* communications between plaintiffs' counsel and their clients' physicians. Rather, it was whether defense counsel should be allowed to meet with treating doctors on the same *ex parte* basis as counsel for the plaintiffs – an issue not raised here. Initially, both parties were allowed to contact plaintiffs' physicians. At plaintiffs' request, Judge Fallon modified his initial ruling, limiting defense counsel access:

> At first blush, the treating physicians in this case seem more like "fact" witnesses than expert witnesses. On closer scrutiny, however, it is clear that the physicians are both fact and expert witnesses. However, with regard to the former, the "facts" that the treating physician has knowledge of were discovered during the time of a private, privileged relationship. To release ***this information*** without the approval of the patient, other than in a deposition or pursuant to a court order, would be in direct conflict with the time honored doctor-patient confidential relationship which has been recognized and protected in both Western and Eastern civilization for over 2000 years.

*Id.* at 476 (emphasis added). Nowhere in Judge Fallon's opinion did he sanction plaintiffs' counsels' "woodshedding" of their clients' physicians with the avowed goal of changing testimony from what it might be to what plaintiffs preferred.[5] Furthermore, because *Vioxx* was withdrawn from the market at the time of the litigation, Judge Fallon faced none of the public health issues present here. He did not need to worry about the potential dangers to patients well

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to prime a non-prescribing cardiologist to give a causation opinion against AbbVie, even though the doctor never held an opinion during his care and treatment that the plaintiff's injury was caused by AndroGel.

[5] A Motion similar to AbbVie's submission in this case was recently filed before Judge Fallon in the *In Re: Xarelto (Rivaroxaban) Products Liability Litigation*, No. 14-md-02592 currently pending in the Eastern District of Louisiana on January 6, 2016. Motion for Entry of Proposed Order Regarding Contact with Physicians by Defendants, *In Re: Xarelto (Rivaroxaban) Prods. Liab. Litig.*, No. 14-md-2592 (E.D. La. Jan. 6, 2016), Dkt. No. 1844. The Motion was taken under advisement on January 22, 2016 and has not yet been ruled on. *Id.* at Dkt. No. 1957.

beyond this litigation if plaintiffs' lawyers put themselves as direct advisors and medical authorities for doctors, empowered to engage in their own potentially "off label" discussions about how they view the risks and benefits of an FDA-approved medication.

Moreover, there is no uniform presumption that plaintiffs are even entitled to the privilege that AbbVie's proposed order accepts for purposes of certainty and ease of litigation management. Although Plaintiffs are correct that Illinois law prohibits substantive defense contacts, Illinois is not the body of law at issue. Rather, it is the substantive law of the bellwether plaintiffs that is significant and none of them is domiciled in Illinois. The 32 bellwether plaintiffs hail from 19 different states. Of those, ***10*** states[6] (totaling 13 plaintiffs) allow defendants to freely contact Plaintiffs' physicians while an eleventh, Colorado, allows for such contacts if certain conditions are met.[7] In the interest of uniformity and to prevent future disputes, AbbVie is willing to forgo their right to these contacts. But it is only fair that there be some limits on Plaintiffs' counsel too. The PSC should not be allowed to invoke a physician-patient privilege as justification for interfering with doctors' testimony, potentially changing memories or creating new memories or opinions that would not otherwise exist. "The privilege was never intended . . . to be used as a trial tactic by which a party entitled to invoke it may control to his advantage the timing and circumstances of the release of information he must

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[6] *See, e.g., Heller v. Norcal Mut. Ins. Co.*, 876 P.2d 999, 1005 (Cal. 1994) (permitting informal interviews provided counsel comply with the state's confidentiality of medical information act); *In re Collins*, 286 S.W.3d 911, 919-20 (Tex. 2009) (permitting *ex parte* contacts by defendants); *Stempler v. Speidell*, 495 A.2d 857, 864-65 (N.J. 1985) (same); *Harris v. Whittington*, No. 06-1179-WEB, 2007 WL 164031, at *1 (D. Kan. Jan. 19, 2007); *Roberts v. Estep*, 845 S.W.2d 544, 547 (Ky. 1993); *Zaden v. Elkus*, 881 So.2d 993, 1012-13 (Ala. 2003); *Bouchard v. Am. Home Products Corp.*, 213 F.Supp.2d 802, 805 (N.D. Ohio 2002); *Felder v. Wyman*, 139 F.R.D. 85, 88 (D.S.C. 1991); *Domako v. Rowe*, 475 N.W.2d 30, 36 (Mich. 1991); *Butler-Tulio v. Scroggins*, 774 A.2d 1209, 1224-25 (Md. Spec. App.), *cert. denied*, 783 A.2d 221 (Md. 2001).

[7] *Samms v. Dist. Court, Fourth Judicial Dist. Of State of Colo.*, 908 P.2d 520, 526 (Colo. 1995) (*ex parte* interviews permissible only after notice to plaintiff and limited to medical matters waived by plaintiff in litigation).

inevitably see revealed at some time." *In re Chantix (Varenicline) Prods. Liab. Litig.*, 2011 WL 9995561, at *3 (quoting *Doe v. Eli Lilly & Co.*, 99 F.R.D. 126, 128 (D.D.C.1983)). AbbVie's proposed order more than adequately protects patients' interests while still ensuring a reasonably even playing field and an equal opportunity for each side to gain unbiased testimony from significant medical witnesses.

### B. AbbVie's Lawful Promotional and Educational Efforts Do Not Justify Allowing Plaintiffs' Lawyers to Change Doctors' Independent Testimony

The PSC devotes much of its brief to the curious argument that AbbVie's historical contact with physicians who were AbbVie customers, and who may have prescribed (and possibly still prescribe) AndroGel as well as potentially other AbbVie medicines, constitutes its own "woodshedding" that the PSC now must remedy. The PSC makes this argument while also claiming (without any apparent awareness of the inherent contradiction in their argument) that this Court need not fear harm from any *ex parte* communications with Plaintiffs' counsel as doctors are not apt to be influenced by what they are told by in these off-the-record conversations. Plainly, if there were no point in Plaintiffs' counsel having these private coaching sessions, the PSC would not want the order they seek and there would be nothing for this Court to decide. This is a live issue because everyone knows that the PSC believes the *ex parte* contacts benefit them strategically. Moreover, the factual and logical mistakes in the PSC's argument are patent and only highlight why it should be rejected.

First, the PSC's claim that AbbVie distributed "false and misleading materials to physicians and the public with no limits on what was said or sent" is so plainly untrue that it is surprising they would have the temerity to stake out such a position. The PSC is well aware that promotional materials for prescription pharmaceuticals are subject to stringent regulations, that AbbVie's promotional materials were repeatedly submitted to and approved by FDA, and that in

15 years of marketing AndroGel, AbbVie never received any letters from FDA criticizing any of the materials it used with doctors or consumers.[8] In addition, the Food and Drug Administration Modernization Act ("FDAMA") passed by Congress in 1997 and related FDA Guidances speak to significant limitations on what and how medical information and materials can be shared with healthcare professionals.[9] In this way, companies' promotional statements for their prescription medicines are kept consistent with their FDA-approved label, and are neither false nor misleading. In other words, the structure in which AbbVie has operated is the exact opposite of what the PSC asks for itself.[10]

Second, and even more importantly, the PSC's arguments ignore the fact that AbbVie's contacts with specific doctors as well as its promotional efforts generally were not undertaken to influence litigation testimony, which is what the PSC wants to do. They were undertaken as part of AbbVie's normal pharmaceutical business. AbbVie's activities are no less part of the historical record than the journal articles and popular media coverage (including unfavorable coverage and coverage featuring plaintiffs' lawyers representing plaintiffs in this litigation), to which the doctors may have been exposed independently.[11] AbbVie's promotional efforts were

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[8] *See, e.g.*, Dep. of Brooke Kim, Vol. II 505:9-19 (Oct. 29, 2015) (excerpts attached as Ex. 1) ("Q. Do you know one way or another whether AbbVie ever received any untitled letters related to AndroGel? A. They have not. Q. Have they received any warning letters related to AndroGel? A. They have not. Q. Have they received any kind of enforcement action from the FDA related to AndroGel? A. They have not.")

[9] *See* Full Text of FDAMA law, http://www.fda.gov/downloads/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDAMA/FullTextofFDAMAlaw/UCM089145.pdf; FDAMA Guidance - Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (January 2009), http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm.

[10] The PSC also greatly exaggerates the nature of the financial "relationship" between Plaintiffs' doctors and AbbVie. Of the 26 doctors who they claim received "monetary payments," all but 3 actually received nothing more than the value of a meal provided at a meeting. Only 1 physician was ever a paid speaker on AbbVie's behalf.

[11] *See, e.g., Are Low-T medications worth the risk?*. (WKMG-TV News 6, Orlando Fla., June 24, 2014) *available at* http://www.clickorlando.com/news/are-low-t-medications-worth-the-

not an attempt to influence the litigation record comparable to what the PSC wants to do; they are part of the factual record. Since discovery of doctors is intended to learn what happened in the care of the plaintiffs and what was known or believed at the time regarding AbbVie's medicine, it is essential the parties obtain physician testimony on these subjects as free of extraneous taint as possible. Having lawyers intervene to change or shape that recollection or create new testimony about that recollection is directly antithetical to a proper discovery process.

Of course, if the PSC believes these lawful contacts influenced a physician's medical judgment more than the physician's education, experience, and knowledge, they are free to pursue such an inquiry. If the PSC wishes to question Plaintiffs' prescribing physicians about documents he may or may not have seen with a goal of refreshing recollection, and/or to inquire about the propriety of AbbVie's conduct, they also may do so. They simply should ask those questions in the context of an on-the-record proceeding and in the presence of AbbVie's counsel where incomplete or inaccurate versions of the historical narrative can be corrected in real time, rather than days or weeks later after the bias has already formed.

Contrary to the PSC's accusations, there was nothing insidious about AbbVie's educational interactions with healthcare providers. Either way, the PSC's accusations provide no justification for allowing unfettered *ex parte* communications with Plaintiffs' physicians to further the PSC's transparent attempt to ***alter*** testimony.

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risk_20151107084331834. In fact, lawyer TV ads soliciting AndroGel plaintiffs began at least as early as January 2014 and became increasingly pervasive over time. There is no reason to think at this point that some or all of the doctors have not been negatively influenced already by the Plaintiffs' bar's litigation promotional campaigns.

### C. If the Court Does Permit Plaintiffs To Have Unfettered *Ex Parte* Contacts, It Should Require Advance Disclosure of All Materials Shown and Allow Counsel for AbbVie to Question Every Physician First at Their Deposition

In almost every case the PSC cites where plaintiffs' counsel were permitted to discuss litigation matters beyond the doctor's medical treatment, the court still imposed significant restrictions. For example, in the *In re Yasmin & Yaz* case cited by Plaintiffs, the Court required that "[d]ocuments provided to treating physicians during such *ex parte* communications may not contain notes, highlighting, underlining, Plaintiff supplied redactions or any other markings that modify the document or direct a reader's attention to a particular portion of the document" and that "Plaintiffs must provide the Defendants precise designations, descriptions or copies of all documents provided to treating physicians during such *ex parte* communications at least 72 hours prior to the treating physician's deposition." *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 9996459 at *2 (S.D. Ill. Mar. 4, 2011). Other orders cited by the PSC reached similar conclusions, designed to curb some of the potentially worst abuses and give the defendants some chance to prepare for how the doctors have been primed to testify.[12]

AbbVie asks that should the Court be inclined to allow the PSC unfettered *ex parte* access to Plaintiffs' physicians, it still include in its case management order, at a minimum, three restrictions to minimize the prejudice to AbbVie. First, as was done in the *In re Yasmin & Yaz* MDL, the PSC should not be permitted to alter, add emphasis to, or provide only parts of documents to the physician. Second, Plaintiffs' counsel should be required to disclose all documents shown to and/or discussed with a physician at least 72 hours prior to the physician's deposition to avoid unfair surprise. Failure to disclose those documents in a timely fashion should preclude Plaintiff from introducing any testimony from that physician related to those

[12] *See* Pl.'s Submission at 7-9 and accompanying exhibits.

documents at trial. Finally, if Plaintiffs' counsel are permitted to meet with physicians prior to their depositions and discuss the substance of the lawsuit, the Court should treat the physicians as Plaintiffs' witnesses and order that AbbVie's counsel be allowed to question Plaintiffs' physicians first at their depositions, regardless of which party served the original deposition notice. Plaintiffs should not be allowed to both secretly coach key witnesses and then take the lead in "deposing" them to elicit the testimony they have endeavored to script.

**D. Plaintiffs' Scheduling Proposal Will Only Cause Unnecessary Discovery Delays**

As set out in AbbVie's submission, there is no reason for the PSC's insistence on having the exclusive, or even primary right to contact physicians' offices for purposes of deposition scheduling. Plaintiffs claim they only want exclusivity for seven days to avoid multiple calls to doctors' offices resulting in confusion and duplication of effort. But Plaintiffs really want more control than they pretend and it is clear they could keep AbbVie from moving forward for much longer. Plaintiffs' proposal is that they lose exclusivity to schedule a deposition after a seven day period except where there is "a reasonable basis" for their failure to do so. Nowhere is "reasonable basis" defined or is it said who determines whether Plaintiffs' failure to schedule the deposition was "reasonable." The potential for abuse of this provision is patent. Further, to the extent the PSC is worried about "multiple firms calling the same physician and confusion" there is an easy solution. The parties can share their lists of physicians to be deposed at this stage across cases and can then divide the bellwether cases so that there is a reasonably even split between the sides as a group, even if not on a case-by-case basis. In this way, the opportunity to promptly schedule depositions should be distributed reasonably evenly and with less potential for delay and abuse by one side.

## CONCLUSION

For the foregoing reasons, AbbVie requests the Court adopt its proposed Case Management Order regarding *ex parte* communications and reject Plaintiffs' counter-proposal.

Dated: February 8, 2016

Respectfully submitted,

By: */s / David M. Bernick*

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**CERTIFICATE OF SERVICE**

I, Christopher R. Boisvert, hereby certify that on February 8, 2016, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

*/s/ Christopher R. Boisvert*